



The Clinical Pharmacology Unit in the Department of Pharmacy Practice and Science is an expert clinical research resource for UMB clinical investigators, contract research organizations and the pharmaceutical industry.

The CPU assists investigators in optimizing their phase I-IV study designs and dosing plans. Our recommendations accommodate the complexities of drug-drug interactions, the disease and the health conditions of the trial participants. We have expertise in hepatic and renal function testing, toxicity and drug metabolism. CPU laboratories conduct pharmacokinetic (PK), pharmacodynamic (PD), and absorption, distribution, metabolism, and elimination (ADME) studies.

The CPU also provides consultation in regulatory submissions, and provides scientific input for clinical protocols, clinical development plans, investigator brochures, and clinical pharmacology sections of IND and NDA submissions.

The CPU evaluates clinical trial data using advanced analytical techniques, performs clinical trial simulations and applies novel pharmacometric principles to clinical trial protocols.

Department of Pharmacy Practice & Science

CLINICAL PHARMACOLOGY UNIT

expertise for clinical
researchers in academia and
the pharmaceutical industry

CLINICAL PHARMACOLOGY UNIT

Department of Pharmacy Practice & Science
540 Allied Health Building, Baltimore, MD 21201

SOPCPU@rx.umaryland.edu

(410) 706-6522 Phone

(410) 706-6850 Fax

<http://www2.pharmacy.umaryland.edu/pps/cpu>



... testing, analyses and FDA expertise for clinical researchers in academia and the pharmaceutical industry



UNIVERSITY OF MARYLAND
SCHOOL OF PHARMACY

The **Clinical Pharmacology Unit** offers a broad spectrum of expertise and services in the early and advanced clinical development of pharmaceutical compounds, new formulations, and new systems of drug delivery. CPU faculty apply their knowledge of human disease, chemistry, drug administration and drug-drug interactions to assist clinical investigative teams in maximizing the efficacy and reducing the toxicity of pharmacotherapeutic agents.

CPU customizes its approach to meet the client's need. Services may include protocol review, dosing plans, and interpretation of PK/PD phase I-IV trials sample data. Results are prepared in accordance with FDA guidance in the development of the Investigation New Drug (IND) submissions, New Drug Applications (NDA) and Investigational Brochures.

SERVICES The CPU conducts state-of-the art laboratory analysis of pharmacotherapeutic compounds and formulations in a variety of biological matrices. This includes ADME, PK, and PD studies. Working with clinical investigators in academic research units, pharmaceutical industry and CROs, the CPU offers customized solutions for our clients' clinical research needs.

- Clinical Trial modeling and simulations
- Phase I and II clinical trial design and protocol review
- Test drug elimination in clinical studies
- Design and conduct renal function studies & cotinine analyses
- Measure GFR and renal blood flow in study subjects
- Perform cellular studies i.e. drug uptake, transport and liver metabolism
- Analyze study data using PK and PD techniques
- Conduct ADME analysis of experimental compounds
- Perform pharmacogenetic sub-analysis using advanced laboratory techniques in genotyping and phenotyping
- Conduct animal pharmacokinetic distribution and toxicology studies
- Prepare Clinical Pharmacology sections of FDA applications

Kenneth Bauer, Pharm.D., Ph.D., CPU Director and Associate Professor. Expertise: Trial design, FDA guidance, pharmacokinetics, drug toxicity, pharmacodynamics, and advanced statistical and analytical techniques. kbauer@rx.umaryland.edu or (410) 706-3274.



Thomas C. Dowling, Pharm.D., Ph.D., Associate Professor. Expertise: Renal function assessment, phenotyping (CYP 3A, 1A), cotinine, trial design and advanced computerized trial analyses and modeling. tdowling@rx.umaryland.edu and (410) 706-0884.



James Polli, Ph.D., Professor. Expertise: Bioavailability considerations in drug design, pharmacokinetics, and drug structure-permeability. jpolli@rx.umaryland.edu or (410) 706-8292.



Natalie D. Eddington, Ph.D., Dean and Professor. Expertise: Pharmacokinetics, population modeling, pharmacodynamics, and compounds targeting the blood-brain barrier and CNS response. neddingt@rx.umaryland.edu or (410) 706-6710.



FEE SCHEDULE (effective 10/1/07)

Clinical Pharmacologist \$160-\$209 per hour

Laboratory Assays \$84-\$110 per hour

Call (410) 706-6522 or contact one of the CPU experts for a free estimate.